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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,104	01/23/2006	Henry Daniell	CHL-T109XC1	6977

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EXAMINER	
KUBELIK, ANNE R	

ART UNIT	PAPER NUMBER
1638	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,104	DANIELL, HENRY	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) *28-32 and 50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27,33-40,45-49,51 and 52* is/are rejected.

7)☒ Claim(s) *41-44* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 January 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election of Group I (claims 1-27, 33-40 and 50) in the reply filed on 17 July 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

As claims 41-44 would fall within this group, they will be examined for the purpose of objecting to them as being improperly multiply dependent.

Claims 28-32 and 50 are withdrawn from consideration as being drawn to non-elected inventions.

2. The drawings filed 3 January 2005 are objected to because the lettering in the arrows and/or boxes in Fig 1A, 2A, 3A, 3B, and 11 cannot be made out.

Corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. See 37 CFR 1.85(a) and MPEP 608.02(b).

3. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892 or by Applicant on form PTO-1449, they have not been considered.

Claim Objections

4. Claims 41-44 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

5. Claims 6, 25, 356 and 51 are objected to because of the following informalities:

In claim 6, line 2, the comma after "5'" should be deleted.

In claim 25, line 1, --, said method-- should be inserted after "IFN".

In claim 35, --said plant-- should be inserted after "35,".

In claim 51, line 2, --said vector-- should be inserted after "genome,".

6. Claims 7-9, 12 and 26-27 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 7 fails to recite any structural difference between the vector in that claim and that in parent claim 1, thus, claim 7 and its dependent claims, fail to further limit claim 1. Claim 12 fails to recite any structure that changes with the intended use of the vector; thus, claim 12 fails to further limit claim 1. The IFN produced in the method of claim 25 would inherently produce an immunogenic response in a mammal; thus, claim 26 fails to further limit claim 25. The immunogenic response would inherently be free of negative side effects; thus, claim 27 fails to further limit claims 26 and 25.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 9, 40 and 45-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claim is directed to a specific tobacco variety, LAMD-609.

Since the variety claimed is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If a seed is not so obtainable or available, a deposit thereof may satisfy the requirements of 35 U.S.C. 112. The specification does not disclose a repeatable process to obtain the exact same seed in each occurrence and it is not apparent if such a seed is currently available to the public. If the deposit of these seeds is made under the terms of the Budapest Treaty, then an affidavit or declaration by the Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the seeds will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. A minimum deposit of 2500 seeds is considered sufficient in the ordinary case to assure availability through the period for which a deposit must be maintained.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit, meets the criteria set forth in 37 CFR 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.801 - 1.809 [MPEP 2401-2411.05] for additional explanation of these requirements.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 4-5, 14, 16-17, 19, 25-27, 33-34, 45-49 and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claims 4 and 17 lack antecedent basis for the limitation "said plastid genome".

Claim 14 lacks antecedent basis for the limitation "said regulatory sequences".

In claim 16 it is unclear if the IFN containing cassette is in addition to the DNA sequence coding for IFN, as recited in claim 1, or if it is an additional IFN coding sequence.

Claim 17 is indefinite in its recitation of "wherein said DNA sequence coding for therapeutic human interferon IFN is located in a single copy region of said plastid genome." This makes no sense as the DNA sequence coding for therapeutic human interferon IFN is in a vector, not in a portion of a plastid genome. Or is this intended to indicate that a portion of a plastid genome is part of the vector?

Claims 25 and 33 are indefinite in their recitation of the abbreviation "IFN".

Claim 33 lacks antecedent basis for the limitation "said recombinant therapeutic human interferon IFN".

Claim 34 is indefinite in its recitation of "extracting IFN from leaves of a stably transformed plant isolating IFNα2b from other plant proteins". Words appear to be missing between "plant" and "isolating". Further, IFNα2b cannot be isolated unless that is what the vector of claim 1 encodes; however, claim 1 is not so limited.

Claims 45-49 lack antecedent basis for the limitation "the expression of IFN".

The term "substantially homologous" in claim 51 is a relative term which renders the claim indefinite. The term "substantially homologous" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. How homologous is "substantially homologous"? .

11. Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are regenerating the plant cell made in claim 33 into a plant, so that IFN can be extracted from leaves, as recited in claim 34.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1, 3-4, 7, 10, 12, 20, 23-27, 33 and 35-38 are rejected under 35 U.S.C. 102(b) as being anticipated by McBride et al (US Patent Publication 2002/0053094, filed July 1998).

McBride et al disclose plastid transformation vectors comprising regions of homology to a plastid genome flanking the selectable marker *aadA* and a construct comprising a plastid promoter operably linked to a sequence encoding interferon operably linked to a transcription termination region, plastids, plant cells, plants and seeds transformed with the construct and method of producing interferon in a plant cell (claims 1-2, 11, 25, 28-31). All plants are edible for some organism.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a), which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 1, 3-5, 7, 10-12, 15-17, 20, 23-27, 33, 35-38 and 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over McBride et al (US Patent Publication 2002/0053094, filed July 1998) in view of Daniell (WO 99/10513 A1).

The claims are drawn to a plastid transformation and expression vector comprising an expression cassette comprising a plastid promoter, a selectable marker sequence, a heterologous DNA encoding human interferon, and a plastid transcription termination region, wherein the vector also comprises flanking sequences homologous to plastid DNA, and methods of using the vector in plastid transformation, and wherein the plant is Petit Havana.

The teachings of McBride et al are discussed above. McBride et al do not teach flanking sequences homologous to transcriptionally active spacer regions in the plastid DNA, including *trnI* and *trnA*.

Daniell teaches a plastid transformation and expression vector comprising an expression cassette comprising the *Prrn* (16SrRNA) plastid promoter, a selectable marker sequence (*aadA*), a heterologous DNA encoding a pharmaceutical protein, and a plastid transcription termination region (*psbA* 3'), wherein the vector also comprises flanking sequences homologous to transcriptionally active spacer regions in the plastid DNA (the *rbc1* and *orf512* genes or the *trnI* and *trnA* genes), methods of using the vector in plastid transformation, and Petit Havana tobacco plants, seed and progeny thereby obtained (pg 26, lines 29-37; pg 29, line 19, to pg 33, line 19; pg 42, line 10, to pg 43, line 26; pg 51, line 12, to pg 60, line 9; Fig 3A; claims 1-2, 85-86, 100-103 and 111-113). The transcription termination region is a 3' untranslated region capable of conferring transcript stability to the protein. The plastids in tobacco leaves would be chloroplasts. Tobacco is edible. Daniell do not disclose plastid transformation vectors encoding human interferon.

McBride et al teach plastid transformation vectors encoding interferon (claim 11). The plastid transformation vectors also comprise 5' untranslated regions (claims 3-4)

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the plastid transformation and expression vectors taught by Daniell, to encode human interferon as described in McBride et al. One of ordinary skill in the art would have been motivated to express interferon in Daniell vectors over those taught by McBride because of the superiority of the Daniell vectors (pg 6, line 28, to pg 7, line 7; pg 9, line 1, to pg

10, line 3, pg 11, lines 9-18) and because of the suggestion of Daniell to express high-value biopharmaceutical proteins in plastids using his vectors (pg 13, line 26, to pg 14, line 22; pg 30, line 30, to 33, line 19). It would be obvious to one of skill in the art to express a human interferon, as this is the most economically desirable form. At least some plants would produce IFN at about 18.5% total soluble protein, and it would be obvious to one of skill in the to select for plants that produced IFN at that rate or higher, to increase the yield of this economically desirable product.

16. Claims 1, 3-4, 6-7, 10, 12-14, 18-20, 23-27, 33 and 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over McBride et al (US Patent Publication 2002/0053094, filed July 1998) in view of in view of Maliga et al (1999, US Patent 5,877,402).

The claims are drawn to a plastid transformation and expression vector comprising an expression cassette comprising a plastid promoter, the *psbA* 5' and/or 3' untranslated region or the *psbA* promoter, a selectable marker sequence, a heterologous DNA encoding human interferon, and a plastid transcription termination region, wherein the vector also comprises flanking sequences homologous to plastid DNA, and methods of using the vector in plastid transformation.

The teachings of McBride et al are discussed above. McBride et al do not teach *psbA* UTRs in the vector.

Maliga et al teach plastid transformation and expression vectors comprising *psbA* 5' and 3' untranslated regions and the *psbA* promoter (Fig 22B and C).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the plastid transformation vector taught by McBride et al, to include the *psbA* 5'

untranslated region described in Maliga et al. One of ordinary skill in the art would have been motivated to do so because of the ribosome binding sites present (Maliga et al, column 24, lines 63, to column 25, line 3) and because use of the *psbA* 5' UTR resulted in high expression levels (column 62, lines 56-65). Selection of the *psbA* 3' UTR is a design choice from among commonly used 3' UTRs in plastid transformation vectors.

17. Claims 1-4, 7, 10, 12, 20, 23-27, 33, 35-38 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over McBride et al (US Patent Publication 2002/0053094, filed July 1998) in view of Chandrasegaran (1999, US Patent 5,792,640).

The claims are drawn to a plastid transformation and expression vector comprising an expression cassette comprising a plastid promoter, a selectable marker sequence, a heterologous DNA encoding human interferon comprising a histidine tag and a thrombin cleavage site, and a plastid transcription termination region, wherein the vector also comprises flanking sequences homologous to plastid DNA, and methods of using the vector in interferon production from plant cells.

The teachings of McBride et al are discussed above. McBride et al do not teach a histidine tag and a thrombin cleavage site in the interferon.

Chandrasegaran teaches expression of heterologous protein in plant cells, wherein the heterologous protein has a histidine tag and a thrombin cleavage site (column 9, lines 50-59).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of expressing interferon in plant cell plastids as taught by McBride et al, to include a histidine tag and a thrombin cleavage site as described in Chandrasegaran. One of skill in the art would also use an interferon comprising a polyhistidine

tag and thrombin cleavage site because of the ease of isolation the histidine tag affords and the desire to remove the tag after isolation.

18. Claims 1, 3-4, 7-8, 10, 12, 20, 23-27, 33 and 35-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over McBride et al (US Patent Publication 2002/0053094, filed July 1998) in view of Conkling et al (WO 98/56923).

The claims are drawn to a plastid transformation and expression vector comprising an expression cassette comprising a plastid promoter, a selectable marker sequence, a heterologous DNA encoding human interferon, and a plastid transcription termination region, wherein the vector also comprises flanking sequences homologous to plastid DNA, and methods of using the vector in plastid transformation, wherein the plant is low-nicotine tobacco.

The teachings of McBride et al are discussed above. McBride et al do not teach using a low nicotine tobacco for production of pharmaceutical proteins.

Conkling et al teach that a low nicotine tobacco are very attractive for production of pharmaceutical proteins (pg 1, line 12-16; pg 6, line 26, to pg 7, line 2).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of expressing interferon in plant cell plastids taught by McBride et al to use low nicotine tobacco plants as described in Conkling et al. One of ordinary skill in the art would have been motivated to do so because tobacco that does not produce nicotine would have more resources available fir production of the transgene product (Conkling et al pg 6, line 26, to pg 7, line 2) and the nicotine would not be a contaminant in the product. Low-nicotine tobacco would be edible for mammalian consumption.

19. Claims 9, 40 and 45-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over McBride et al in view of Conkling et al as applied to claims 1, 3-4, 7-8, 10, 12, 20, 23-27, 33 and 35-39 above, and further in view of Aycock et al (1998, Crop Science 38:904).

The claims are drawn to a plastid transformation and expression vector comprising an expression cassette comprising a plastid promoter, a selectable marker sequence, a heterologous DNA encoding human interferon, and a plastid transcription termination region, wherein the vector also comprises flanking sequences homologous to plastid DNA, and methods of using the vector in plastid transformation of low-nicotine tobacco, wherein the low-nicotine tobacco is LAMD-609.

The teachings of McBride et al in view of Conkling et al are discussed above. McBride et al in view of Conkling et al do not teach the low nicotine tobacco LAMD-609.

Aycock et al teach the low nicotine tobacco LAMD-609.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to use LAMD-609 taught by Aycock et al in the method of expressing interferon in the plastids of low nicotine tobacco taught by McBride et al in view of Conkling et al. One of ordinary skill in the art would have been motivated to do so because selection of one low nicotine tobacco over another is an obvious design choice. It would be obvious to one of skill in the art to select transgenic events in which the expression of IFN was high, including those in which IFN is 12.5% of the total soluble protein.

20. Claims 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over McBride et al in view of Daniell as applied to claims 1, 3-5, 7, 10-12, 15-17, 20, 23-27, 33, 35-38 and 47-49 above, and further in view of Rathinasabapathi et al (1994, Planta 193:155-162).

The claims are drawn to a plastid transformation and expression vector comprising an expression cassette comprising a plastid promoter, a selectable marker sequence, a heterologous DNA encoding human interferon, and a plastid transcription termination region, wherein the vector also comprises flanking sequences homologous to plastid DNA, and wherein the selectable marker is BADH.

The teachings of McBride et al in view of Daniel are discussed above. McBride et al in view of Daniel do not teach use of BADH as a selectable marker.

Rathinasabapathi et al teach transformation of tobacco plants with a spinach or beet gene encoding BADH (pg 157). The protein is targeted to the chloroplasts (pg 157-158) and the resulting plants are resistant to betaine aldehyde (pg 159-160).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the vectors taught by McBride et al in view of Daniel to use the BADH gene as a selectable marker as described in Rathinasabapathi et al. One of ordinary skill in the art would have been motivated to do so because of the suggestion of Rathinasabapathi et al to use betaine aldehyde resistance as a selectable marker in plants that lack glycine betaine (paragraph spanning the columns, pg 161) and because substitution of chloroplast transformation for chloroplast targeting of a nuclear-encoded gene is an obvious design choice.

21. Claims 34 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over McBride et al in view of Chandrasegaran as applied to claims 1-4, 7, 10, 12, 20, 23-27, 33, 35-38 and 51 above, and further in view of Reichert et al (1995, US Patent 5,460,956).

The claims are drawn to a plastid transformation and expression vector comprising an expression cassette comprising a plastid promoter, a selectable marker sequence), a heterologous

DNA encoding human interferon, and a plastid transcription termination region, wherein the vector also comprises flanking sequences homologous to plastid DNA, and methods of using the vector in plastid transformation, wherein the IFN is IFNα2b.

The teachings of McBride et al in view of Chandrasegaran are discussed above. McBride et al in view of Chandrasegaran do not teach use of IFNα2b.

Reichert et al teach IFNα2b (column 2, lines 49-65).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to express IFNα2b, as taught by Reichert et al in the method of of producing IFN in plastids, as taught by McBride et al in view of Chandrasegaran. One of ordinary skill in the art would have been motivated to do so because IFNα2b is a desirable form for disease treatment (Reichert et al, column 1, lines 15-32).

Double Patenting

22. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

23. Claims 3-20 and 22-26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6, 13 and 18 of copending Application No. 10/520,104. Although the conflicting claims are not identical, they are not patentably distinct from each other because plastid vectors comprising a first flanking sequence, a 5' UTR (including that from psbA), a DNA encoding human interferon, and a second flanking sequence, as claimed in the copending application, are species of the genus of plastid vectors comprising a first flanking sequence, a 5' UTR(including that from psbA), a DNA encoding human interferon, and a second flanking sequence, as claimed in the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

24. No claim is allowed.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, Ph.D., whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the

problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

October 24, 2008

/Anne R. Kubelik/
Primary Examiner, Art Unit 1638